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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| ART UNIT | PAPER NUMBER |
|---|---|
| 1614 | |

DATE MAILED: 02/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. 09/990,955 | Applicant(s) BOOLELL, MITRADEV | |
|---|---|---|---|
| | Examiner Brian S Kwon | Art Unit 1614 | |

*-- The MAILING DATE of this communication appears on the cov r sheet with the correspond nce address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *16 November 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

## DETAILED ACTION

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in-
> 1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
> (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

1. Claims 1-8 and 11 are rejected under 35 U.S.C. 102(e) as being anticipated by Lee et al. (US 6512002 B2).

Lee teaches the use of co-administration of estrogen agonists/antagonists and cGMP PDEv inhibitor (e.g., sildenafil) for the treatment of premature ejaculation (column 21, lines 19-23; claims 3 and 5). The reference discloses that the the cGMP PDEv inhibitors have an IC50 for PDEv at less than 100 nanomolar, more preferably, at less than 50 nanomolar, more prefereably still at less than 10 nanomolar (column 23, lines 51-54); the cGMP PDEv inhibitors are selective over PDEiii, more preferably over PDEIII, and PDEiv (column 23, lines 59-62); and the cGMP PDEv inhibitors have a selectivity ratio greater than 100 more preferably greater than 300, over PDEiii and more preferably over PDEiii, and PDEiv (column 23, lines 62-65). The reference also discloses that the claimed composition is preferably administered in different dosage forms including oral administration (column 41, lines 21-23).

Since the instant claims recite "comprising" language, the reference clearly anticipates the claimed invention.

2. Claims 1-11 are rejected under 35 U.S.C. 102(e) as being anticipated by Wilson et al. (US 6403597 B1).

Wilson teaches the use of type V phosphodiesterase inhibitor such as sildenafil for treating premature ejaculation (abstract; column 4, lines 9-18; claims). The reference also teaches the claimed oral administration (claims 15, 17-19, 21, 40-44 of US'597) as required in claim 8 and the claimed dosage amount of phosphodiesterase inhibitor (e.g., sildenafil citrate), in the range of about 1 mg to about 250mg, typically in the range of about 15mg to about 100mg (column 22, line 65 thru column 23, line 7), as required in claims 9-10.

Although the reference is silent about "PDE5 inhibitor has an IC 50 against the PDE 5 enzyme of less than 100 nanometer" in claim 3; "PDE5 inhibitor has selectivity over PDE 3 of greater than 100 fold" in claim 4; "PDE5 inhibitor PDE5 inhibitor has selectivity over both PDE 3 and PDE 4 of greater than 100 fold " in claim 5; and "PDE5 inhibitor has an IC 50 against the PDE 5 less than 100 nM and a selectivity over PDE3 of greater than 100 fold" in claim 6, such characteristics or properties are deemed to be inherent to the composition, i.e., it was always there.

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Doherty, Jr. et al. (US 6037346 A), if necessary, and further in view of Crenshaw et al. (US 5276042) and Crenshaw et al. (5151448) and/or Bick (US 4940731).

Doherty teaches or suggests the use of type V phosphodiesterase inhibitor (e.g., sildenafil, pyrazolopyrimidinone, zaprinast) for treating premature ejaculation, mainly in local administration. The reference also teaches that PED5 inhibitor is given a daily in the rage of approximately 0.1 to 500mg/day.

Crenshaw'042, '448 and '731 teach the use of anidepressants such as fluoxetine, paroxetine and/or sertraline for the treatment of premature ejaculation.

The teaching of Doherty differs from the claimed invention in the use of PDE 5 inhibitor in "normal erectile function" (claims 1-11) and in oral form (claim 8).

Although the reference is silent about the efficacy of PDE5 inhibitor in the treatment of premature ejaculation with "normal erectile function" patient, one having ordinary skill in the art would have motivated to apply the claimed PDE5 inhibitor (e.g., sildenafil), with reasonable expectation of success, to treat patients with premature ejaculation regardless of normal erectile function or erectile dysfunction. One having ordinary skill in the art would have known that PDE5 inhibitor would be effective in treating premature ejaculation in patients with "normal erectile function" as well as erectile problem patient. The state of the premature ejaculation treatment art does not distinguish between patient with "normal erectile function and patient with erectile function problem. Rather, the prior art generally teaches that any effective agents for the treatment of premature ejaculation would be effective in treating

premature ejaculation regardless of "normal erectile function" or erectile problem. Based on the state of the prior art, differences in "normal erectile function" will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such "normal erectile function" is critical.

In addition, the determination of dosage form having optimum therapeutic index is well considered within the skill of the artisan, absent evidence to the contrary.

***Conclusion***

4. No Claim is allowed.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Kwon whose telephone number is (703)308-5377. The examiner can normally be reached Tuesday through Friday from 9:00 am to 7:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, can be reached on (703) 308-4725. The fax number for this Group is (703) 308-4556.

Any inquiry of a general nature of relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

Brian Kwon

**ZOHREH FAY**
**PRIMARY EXAMINER**
**GROUP 1600**